information about your device that will allow us better to define the scope of a surveillance order. We will specify the device(s) subject to the surveillance order and the reason that we are requiring postmarket surveillance of the device under section 522 of the act. We will also provide you with any general or specific guidance that is available to help you develop your plan for conducting postmarket surveillance.

§ 822.6 When will you notify me that I am required to conduct postmarket surveillance?

We will notify you as soon as we have determined that postmarket surveillance of your device is necessary, based on the identification of a surveillance question. This may occur during the review of a marketing application for your device, as your device goes to market, or after your device has been marketed for a period of time.

§ 822.7 What should I do if I do not agree that postmarket surveillance is appropriate?

(a) If you do not agree with our decision to order postmarket surveillance for a particular device, you may request review of our decision by:

(1) Requesting a meeting with the Director, Office of Surveillance and Biometrics, who generally issues the order for postmarket surveillance;

(2) Seeking internal review of the order under § 10.75 of this chapter;

(3) Requesting an informal hearing under part 16 of this chapter; or

(4) Requesting review by the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee.

(b) You may obtain guidance documents that discuss these mechanisms from the Center for Devices and Radiological Health's (CDRH's) Web site (*http://www.fda.gov/cdrh/ombudsman/dispute.html*).

[67 FR 38887, June 6, 2002, as amended at 72 FR 17399, Apr. 9, 2007]

Subpart C—Postmarket Surveillance Plan

§ 822.8 When, where, and how must I submit my postmarket surveillance plan?

You must submit your plan to conduct postmarket surveillance within 30 days of the date you receive the postmarket surveillance order. For devices regulated by the Center for Biologics Evaluation and Research, send three copies of your submission to the Document Control Center (HFM–99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. For devices regulated by the Center for Drug Evaluation and Research, send three copies of your submission to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B, Ammendale Rd., Beltsville, MD 20705–1266. For devices regulated by the Center for Devices and Radiological Health, send three copies of your submission to the Document Mail Center, 10903 New Hampshire Ave., Bldg. 66, rm. G609, Silver Spring, MD 20993–0002. When we receive your original submission, we will send you an acknowledgment letter identifying the unique document number assigned to your submission. You must use this number in any correspondence related to this submission.

[75 FR 20915, Apr. 22, 2010]

§ 822.9 What must I include in my submission?

Your submission must include the following:

(a) Organizational/administrative information:

(1) Your name and address;

(2) Generic and trade names of your device;

(3) Name and address of the contact person for the submission;

(4) Premarket application/submission numbers for your device;

(5) Table of contents identifying the page numbers for each section of the submission;

(6) Description of the device (this may be incorporated by reference to the appropriate premarket application/submission);

(7) Product codes and a list of all relevant model numbers; and
(8) Indications for use and claims for the device;
(b) Postmarket surveillance plan;
(c) Designated person information;
(1) Name, address, and telephone number; and
(2) Experience and qualifications.

§ 822.10 What must I include in my surveillance plan?

Your surveillance plan must include a discussion of:
(a) The plan objective(s) addressing the surveillance question(s) identified in our order;
(b) The subject of the study, e.g., patients, the device, animals;
(c) The variables and endpoints that will be used to answer the surveillance question, e.g., clinical parameters or outcomes;
(d) The surveillance approach or methodology to be used;
(e) Sample size and units of observation;
(f) The investigator agreement, if applicable;
(g) Sources of data, e.g., hospital records;
(h) The data collection plan and forms;
(i) The consent document, if applicable;
(j) Institutional Review Board information, if applicable;
(k) The patient followup plan, if applicable;
(l) The procedures for monitoring conduct and progress of the surveillance;
(m) An estimate of the duration of surveillance;
(n) All data analyses and statistical tests planned;
(o) The content and timing of reports.

§ 822.11 What should I consider when designing my plan to conduct postmarket surveillance?

You must design your surveillance to address the postmarket surveillance question identified in the order you received. You should consider what, if any, patient protection measures should be incorporated into your plan. You should also consider the function, operating characteristics, and intended use of your device when designing a surveillance approach.

§ 822.12 Do you have any information that will help me prepare my submission or design my postmarket surveillance plan?

Guidance documents that discuss our current thinking on preparing a postmarket surveillance submission and designing a postmarket surveillance plan are available on the Center for Devices and Radiological Health's Web site and from the Food and Drug Administration, Center for Devices and Radiological Health, Office of Surveillance and Biometrics, 10903 New Hampshire Ave., Bldg. 66, rm. 3219, Silver Spring, MD 20993–0002. Guidance documents represent our current interpretation of, or policy on, a regulatory issue. They do not establish legally enforceable rights or responsibilities and do not legally bind you or FDA. You may choose to use an approach other than the one set forth in a guidance document, as long as your alternative approach complies with the relevant statutes (laws) and regulations. If you wish, we will meet with you to discuss whether an alternative approach you are considering will satisfy the requirements of the act and regulations.

[75 FR 20915, Apr. 22, 2010]

§ 822.13 [Reserved]

§ 822.14 May I reference information previously submitted instead of submitting it again?

Yes, you may reference information that you have submitted in premarket submissions as well as other postmarket surveillance submissions. You must specify the information to be incorporated and the document number and pages where the information is located.

§ 822.15 How long must I conduct postmarket surveillance of my device?

The length of postmarket surveillance will depend on the postmarket surveillance question identified in our order. We may order prospective surveillance for a period up to 36 months; longer periods require your agreement. If we believe that a prospective period